

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2000 list were published in the Federal Register in March 2000.

### New Approvals

**ANADA Number: 200-275**

Pioneer Product: 046-146  
Trade Name: Medalone Cream  
Ingredients: Triamcinolone acetonide  
Sponsor: Med-Pharmex, Inc.  
Approval Date: February 4, 2000  
Status: Prescription only  
Route: Topical  
Species: Dogs  
Drug Form: Cream  
Concentration: 1.0 mg triamcinolone acetonide per gram  
Indications: For the topical treatment of allergic dermatitis and summer eczema.

21CFR 524.2481

**NADA Number: 141-146**

Trade Name: Nicarb<sup>®</sup>, Baciferm<sup>®</sup>  
Ingredients: Nicarbazin, bacitracin zinc  
Sponsor: Koffolk, Inc.  
Approval Date: February 2, 2000  
Status: Over-the-counter  
Route: Oral  
Species: Broiler chickens  
Drug Form: Type A Medicated Articles to make combination Type C medicated feeds.  
Concentration: Nicarbazin – 113.5 grams of nicarbazin activity per pound of Type A Medicated Article, Bacitracin zinc – 50 grams of bacitracin activity per pound of Type A Medicated Article.  
Indications: As an aid in preventing outbreaks of cecal coccidiosis (*Eimeria tenella*) and intestinal coccidiosis (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*), for increased rate of weight gain and for improved feed efficiency.  
Tolerance: 21CFR 556.70: Bacitracin: A tolerance for residues of bacitracin zinc or bacitracin methylene disalicylate has been established at 0.5 ppm in uncooked edible tissues.  
21CFR 556.445: Nicarbazin: A tolerance for residues has been established at 4 ppm in uncooked chicken muscle, liver, skin, and kidney.  
Withdrawal: 4 days

21CFR 558.78 and 558.366(c)

**NADA Number: 141-163**

Trade Name: Milbemite<sup>™</sup> Otic Solution  
Ingredients: Milbemycin oxime  
Sponsor: Novartis Animal Health US, Inc.  
Approval Date: February 2, 2000  
Status: Prescription only  
Route: Topical  
Species: Cats and kittens  
Drug Form: Solution  
Concentration: 0.1% milbemycin oxime  
Indications: For the treatment of ear mite (*Otodectes cynotis*) infestations in cats and kittens eight weeks of age and older.  
Patent Number: 4,547,520                      Expiration Date: June 14, 2004  
Exclusivity: 3 years

21CFR 524.1446

### Suitability Petition Action

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**Number:** 99P-5331/CP1  
**Sponsor:** PharmX, Inc.  
**Petition:** Request permission to file an ANADA for a generic new animal drug containing phenylbutazone, which differs from the pioneer product, PhenylBute™, Phoenix Scientific Inc., NADA 091-818 by the following characteristics: the proposed generic product will have a dosage form as palatable pellets as opposed to the pioneer product which is a tablet.  
**Action:** Approved on March 7, 2000

**Number:** 00P-0117/CP1  
**Sponsor:** Phoenix Scientific, Inc.  
**Petition:** Request permission to file an ANADA for a generic new animal drug containing lincomycin hydrochloride and spectinomycin dihydrochloride pentahydrate, which differs from the pioneer product, Pharmacia & Upjohn Co., NADA 046-109 by the following characteristics: the generic product will provide for a product containing spectinomycin dihydrochloride pentahydrate whereas the pioneer product contains spectinomycin sulfate tetrahydrate.  
**Action:** Approved on March 9, 2000

**Number:** 99P-5329/CP1  
**Sponsor:** Tyler Group, Inc.  
**Petition:** Request permission to file an ANADA for a generic new animal drug containing furosemide, which differs from the pioneer product, Lasix®, Hoechst Roussel Vet, NADA 034-621 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.  
**Action:** Approved on March 20, 2000

**Number:** 99P-5330/CP1  
**Sponsor:** Tyler Group, Inc.  
**Petition:** Request permission to file an ANADA for a generic new animal drug containing enalapril maleate, which differs from the pioneer product, Enacard® Tablets, Meril Ltd., NADA 141-015 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.  
**Action:** Approved on March 20, 2000

**Number:** 99P-5328/CP1  
**Sponsor:** Tyler Group, Inc.  
**Petition:** Request permission to file an ANADA for a generic new animal drug containing prednisolone, which differs from the pioneer product, PrednisTab®, Lloyd, Inc., NADA 140-921 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.  
**Action:** Approved on March 21, 2000

**Number:** 00P-0444/CP1  
**Sponsor:** Phoenix Scientific, Inc.  
**Petition:** Request permission to file an ANADA for a generic new animal drug containing spectinomycin dihydrochloride pentahydrate, which differs from the pioneer product, spectinomycin sulfate tetrahydrate (Adspec™ Sterile Solution), Pharmacia & Upjohn Co., NADA 141-077, by the following characteristic: the generic product differs in the salt form of the active drug substance.  
**Action:** Denied on March 22, 2000.

**Number:** 99P-2733/PRC1  
**Sponsor:** Wildlife Laboratories, Inc.  
**Petition:** Request permission for reconsideration to file an ANADA for a generic new animal drug containing ketamine hydrochloride, which differs from the pioneer product, Vetalar, Fort Dodge Animal Health, Division AHP Corp., NADA 045-290 by the following characteristic: the generic product will provide for a product containing 200 mg/mL ketamine hydrochloride whereas the pioneer product contains 100 mg/mL ketamine hydrochloride.  
**Action:** Denied on March 30, 2000.